4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0125]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review--Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0775. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 240-994-7399, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Establishing That a Tobacco Products Was Commercially Marketed in the United States as of February 15, 2007

OMB Control Number 0910-0775--Extension

The Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes FDA to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors. Tobacco products are governed by chapter IX of the FD&C Act (sections 900 through 920) (21 U.S.C. 387 through 21 U.S.C. 387u). Section 910 of the FD&C Act (21 U.S.C. 387j) provides for the submission of applications for review of certain tobacco products. New tobacco products are those products, including those products in test markets, not commercially marketed in the United States as of February 15, 2007, or where the modified tobacco product was commercially marketed in the United States after February 15, 2007 (section 910(a)(1) of the FD&C Act).

To assist new tobacco product manufacturers with requirements in section 910 of the FD&C Act, we developed the guidance document entitled, "Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007" (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/establishing-tobacco-product-was-commercially-marketed-united-states-february-15-2007). The guidance provides information on how a manufacturer may establish that a tobacco product was commercially marketed in the United States as of February 15, 2007. The guidance includes a description of the types of evidence FDA recommends that the manufacturer submit to demonstrate that a tobacco product was commercially marketed in the United States as of February 15, 2007. Examples of such information may include, but are not limited to, the following: dated copies of advertisements, dated catalog pages, dated promotional material, and

dated bills of lading. The guidance also provides instruction on how to submit a request for a Pre-Existing Tobacco Product status review (Section III.B.).[1]

As discussed in the guidance, electronic submission is not required, although we strongly encourage electronic submission via FDA's Electronic Submissions Gateway (ESG) using FDA's eSubmitter tool. FDA's ESG system requires users to apply for a free account before submitting data, a process which can take 1 to 3 weeks to complete. Once approved, the user can send all submissions to CTP using the eSubmitter tool and FDA ESG. Instructions on obtaining an ESG account are available at https://www.fda.gov/industry/electronic-submissions-gateway/create-esg-account. Alternatively, respondents can mail submissions to FDA, as instructed in the guidance.

In the *Federal Register* of December 9, 2021 (86 FR 70139), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

Activity; Guidance Document Sec. III.B	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
Submit evidence of commercial marketing in the United States as of February 15, 2007	1,000	1	1,000	5	5,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA's estimate of the number of respondents is based on the fact that submissions are voluntary and also on the pre-existing status of a tobacco product submissions received. The number of hours to gather the evidence is FDA's estimate of how long it might take a manufacturer to review, gather, and submit dated information if making a request for Agency determination.

[1] FDA changed the term from "grandfathered tobacco product" to "Pre-Existing Tobacco Product" in the recently published final SE (86 FR 55224) and PMTA (86 FR 55300) rules because it more appropriately describes these products by using the more precise term "Pre-Existing" in place of "grandfathered."

FDA further estimates it would take a manufacturer approximately 5 hours to put together this collection of evidence and to submit the package to FDA for review. FDA estimates that it would take approximately 5,000 hours annually to respond to this collection of information.

Dated: April 27, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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